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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,208	11/17/2003	Jian Ni	PF381C1D1	5854
22195	7590	09/22/2004	EXAMINER	
HUMAN GENOME SCIENCES INC INTELLECTUAL PROPERTY DEPT. 14200 SHADY GROVE ROAD ROCKVILLE, MD 20850			HUYNH, PHUONG N	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/713,208

Applicant(s)

NI ET AL.

Examiner

Phuong Huynh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 9-23 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 10-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9 and 13-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

1. Claims 1 and 9-23 are pending.
2. Applicant's election with traverse of Group 4, Claim 9 (now claims 9, and 13-23) drawn to an isolated I-FLICE-2 polypeptide, filed 5/7/04, is acknowledged. The traversal is on the grounds that to search and examine the subject matter of all the Groups together, and in particular, to search Groups 2, 4, 6, 8 and 10 simultaneously, would not entail a serious burden. A search of the amino acid sequence of I-FLICE-2 would surely produce information relevant to the nucleic acid sequence of I-H-ICE-Z, and antibodies that bind to I-FLICE-2. However, if the restriction requirement is maintained, Applicants request rejoinder of the claims of Group 8 once the claims of Group 6 are found allowable. In light of the decisions in *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ 2d 1663 (Fed. Cir. 1996).

This is not found persuasive because of the reasons set forth in the restriction mailed 4/21/04. As is well known in the art, polynucleotides such as are claimed by Applicant are transcribed into RNA and the RNA is translated into protein. Thus polynucleotides encode proteins. Antibodies are proteins that bind to other proteins. The two types of molecules therefore have different functions - the encoding of protein versus binding to other proteins, different modes of operation - transcription and translation versus protein-protein interactions - and different effects - production of protein versus interacting with another protein. Thus, as was stated in the previous office action, they differ structurally and functionally and cannot be used together or interchangeably. Reasons as to why the other groups are distinct are also provided in the previous office action. A product is distinct from a process of use if it has other uses. Methods are different if they have different method steps, goals, or outcome measures. Further, a prior art search also requires a literature search. It is a burden to search more than one invention. With respect to the argument that the search and examination of all groups would not entail a "serious burden", the separate classification of the different groups provides prima facie evidence of such a burden; see MPEP § 803. Furthermore, antibodies, polynucleotides, polypeptides and methods represent different inventions and require different, non-contiguous searches, as evidenced by their different classification. They require separate searches of separate databases. A search of polynucleotide databases does not reveal information about protein sequences, nor

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does a search of polypeptide databases reveal information about polynucleotides. The search for methods of use is separate because it requires additional considerations as to the methodology itself. Thus to consider all of these groups would constitute an undue burden because each requires considerations that are separate from each of the others. It is agreed, however, that, the claims of Group 8 drawn to a method of treating a specific disease or disorder using the elected composition once the claims of Group 6 are found allowable will be rejoined in light of the decisions in *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ 2d 1663 (Fed. Cir. 1996). Applicant is reminded that where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. **Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.** Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Therefore, the requirement of Group 4 (now claims 9 and 13-23) and Groups 1-3 and 5-10 is still deemed proper and is therefore made FINAL.

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3. Claims 1, and 10-12 are withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions.
4. Claims 9, and 13-23, drawn to an isolated I-FLICE-2 polypeptide, are being acted upon in this Office Action.
5. Applicant should amend the first line of the specification to update the relationship between the instant application and 09/489,155, filed 01/21.2000, which is now Pat No. 6,680,171 and 09/009,893 filed 1/21/1998 now Pat No. 6,623,938.
6. Claim 9 is objected to because “;” is missing at the end of (d).
7. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
8. Claims 9, 18, 20, 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that cDNA in ATCC with the Deposit No. 209038 as set forth in claims 9 and 18 is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, a deposit of the clone may satisfy first paragraph. See 37 CFR 1.801-1.809.

If the deposit has been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the cDNA in ATCC with the Deposit No. 209038 has been deposited under the Budapest Treaty and that the cDNA in ATCC with the Deposit No. 209038 will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808. Further, the record must be clear that the

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deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample or **for the enforceable life of the patent whichever is longer**. See 37 CFR 1.806.

If the deposit has not been made under the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit throughout the life of the patent.

9. Claims 9, 13-17, and 19-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (1) an isolated I-FLICE-2 polypeptide comprising an amino acid sequence selected from the group consisting of: amino acids from 1 to 348 in SEQ ID NO: 6, amino acids from 2 to 348 in SEQ ID NO: 6, (2) the said polypeptide wherein the polypeptide is glycosylated for a method of inhibiting apoptosis mediated by TNFR-1 and CD95, **does not** reasonably provide enablement for (1) all isolated I-FLICE-2 polypeptide having an amino acid sequence “at least 95% identical” to amino acid sequence selected from the group consisting of: (a) amino acids from “about 1 to about 75 in SEQ ID NO: 6”; (b) amino acids from “about 76 to about 252 in SEQ ID NO: 6”; (c) amino acids from “about 253 to about 348 in SEQ ID NO: 6”; (d) amino acids from “about 1 to about 348 in SEQ ID NO: 6”; (e) amino acids from “about 2 to about 348 in SEQ ID NO: 6”; and the amino acid sequence of an epitope-bearing portion of any one of the polypeptides mentioned above; (2) all isolated I-FLICE-2 polypeptide wherein the amino acid sequence “comprises” an antigenic region selected from the group consisting of: (i) amino acid residues from “about 62 to about 136 in SEQ ID NO: 6”; (ii) amino acids residues from “about 184 to about 193 in SEQ ID NO: 6” and (iii) amino acid residues from “about 205 to about 341 in SEQ ID NO: 6”, and (3) all fusion protein comprising any isolated I-FLICE-2 polypeptide mentioned above fused to *any* “heterologous polypeptide”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in **scope** with these claims.

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Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

The specification discloses only two I-FLICE polypeptides comprising SEQ ID NO: 2 (I-FLICE-1) and SEQ ID NO: 6 (I-FLICE-2) as shown in Figures 1 and 2 wherein the I-FLICE-2 polypeptide inhibits apoptosis mediated by TNFR-1 and CD95 (Figure 6).

The specification does not teach how to make *any* I-FLICE-2 polypeptide having at least “95% sequence identity” to amino acid sequence set forth in claims 9, 13, 15, 17 and 19 because there is insufficient guidance as to which amino acids within about 1 to about 75 in SEQ ID NO: 6, or within about 76 to about 252 in SEQ ID NO: 6 or within about 253 about 348 in SEQ ID NO: 6 to be substituted, deleted, added or any combination thereof and whether the resulting polypeptide maintains its anti-apoptotic activity. Further, the term “about” expands the specified amino acid residues of SEQ ID NO: 6 to include additional amino acids residues at either or both ends of the recited residues. Given the ambiguity of the specified amino acid residues, there is insufficient guidance as how to make at least 95% sequence identity to the said polypeptide. Likewise, there is insufficient guidance as to which amino acids within the full length sequence from about 1 to about 348 or about 2 to about 348 SEQ ID NO: 6 to be substituted, deleted or added and whether the resulting polypeptide maintains anti-apoptotic activity. A polypeptide with at least 95% identity means at least 5% differences which is equivalent to having at least 18 amino acids modification such as substitution, deletion, addition and combination thereof. There is a lack of working example demonstrating all undisclosed I-FLICE-2 polypeptide mentioned above are effective for inhibiting apoptosis, much less for treating any apoptosis related diseases.

It is known in the art that the relationship between the amino acid sequence of a protein (polypeptide) and its tertiary structure (i.e. its binding activity) are not well understood and are not predictable (see Ngo et al., in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz, et al., (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495).

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There is no recognition in the art that sequence with identity predicts biological function. It is known in the art that even a single amino acid changes or differences in a protein's amino acid sequence can have dramatic effects on the protein's function. Mikayama *et al.*, teach that the human glycosylation-inhibiting factor (GIF) protein differs from human macrophage migration inhibitory factor (MIF) by a single amino acid residue (Figure 1 in particular). Yet, Mikayama *et al.* further teach that GIF is unable to carry out the function of MIF and MIF does not demonstrate GIF bioactivity (Abstract in particular). It is also known in the art that amino acid sequence determines the function of the polypeptide or protein. However, the predictability of which changes can be tolerated in an amino acid sequence and still retain similar functions and properties requires a knowledge of, and guidance such as which amino acids within the full-length polypeptide are tolerant of modification and which amino acid residues are conserved or less tolerant to modification in which the product's structure relates to its functional usefulness.

The use of "percent" in conjunction with any of the various terms that refer to sequence identity or similarity is a problem because sequence identity between two sequences has no common meaning within the art. The term "percent" is relative and can be defined by the algorithm and parameter values set when using the algorithm used to compare the sequences. The scoring of gaps when comparing one sequence to another introduces uncertainty as to the percent of similarity between two sequences. Because applicants have not disclosed the specific condition used to score sequence identity while using any computer program mentioned above, it is unpredictable to determine which amino acid sequences will have at least about 95% identity to the claimed sequence and still retains the activities. In addition to the problem of having "at least 95% identity" mentioned above, the term "about" compounds the problem by extending the lower and upper limits of the amino acids residues in SEQ ID NO: 6 or the full length polypeptide of SEQ ID NO: 6. Further, the term "having" or "comprises" is open-ended. It expands the polypeptide fragment such as the ones recited in claim 21 to include additional amino acids at either or both ends. There is insufficient guidance as to which amino acids to be added and whether the undisclosed has any function, let alone a method of treating any disease using the claimed polypeptide.

Attwood *et al.* teach that protein function is context-dependent and the state of the art of making functional assignments merely on the basis of some degree of similarity between sequences and the current structure prediction methods is unreliable (See figure, entire document).



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Skolnick *et al* teach that sequence-based methods for function prediction are inadequate and knowing a protein's structure does not tell one its function (See abstract, in particular).

It is unpredictable which undisclosed polypeptide having at least about 95 amino acid differences would maintain its structure and biological function such as inhibiting apoptosis by TNFR-1 and/or CD95, in turn, would be useful for treating all diseases associated with apoptosis such as the ones listed on page 27. Further, there is no in vivo working example demonstrating that any isolated polypeptide mentioned above including the full length I-FLICE-2 comprising SEQ ID NO: 6 could treat all diseases associated with apoptosis. Until the activity associated with the polypeptide having at least 95% sequence identity to the polypeptides mentioned above has been identified, the specification merely extends an invitation to one skill in the art for further experimentation to arrive at the claimed invention.

For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of *Ex parte Aggarwal*, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

10. Claims 9, 13-17, and 19-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** for all (1) an isolated I-FLICE-2 polypeptide comprising an amino acid sequence selected from the group consisting of: amino acids from 1 to 348 in SEQ ID NO: 6, amino acids from 2 to 348 in SEQ ID NO: 6, (2) the said polypeptide wherein the polypeptide is glycosylated for a method of inhibiting apoptosis mediated by TNFR-1 and CD95, **does not** reasonably provide enablement for (1) all isolated I-FLICE-2 polypeptide having an amino acid sequence "at least 95% identical" to amino acid sequence selected from the group consisting of: (a) amino acids from "about 1 to about 75 in

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SEQ ID NO: 6"; (b) amino acids from "about 76 to about 252 in SEQ ID NO: 6"; (c) amino acids from "about 253 to about 348 in SEQ ID NO: 6"; (d) amino acids from "about 1 to about 348 in SEQ ID NO: 6"; (e) amino acids from "about 2 to about 348 in SEQ ID NO: 6"; and the amino acid sequence of an epitope-bearing portion of any one of the polypeptides mentioned above; (2) all isolated I-FLICE-2 polypeptide wherein the amino acid sequence "comprises" an antigenic region selected from the group consisting of: (i) amino acid residues from "about 62 to about 136 in SEQ ID NO: 6"; (ii) amino acid residues from "about 184 to about 193 in SEQ ID NO: 6" and (iii) amino acid residues from "about 205 to about 341 in SEQ ID NO: 6", and (3) all fusion protein comprising any isolated I-FLICE-2 polypeptide mentioned above fused to *any* "heterologous polypeptide".

The specification discloses only two I-FLICE polypeptides comprising SEQ ID NO: 2 (I-FLICE-1) and SEQ ID NO: 6 (I-FLICE-2) as shown in Figures 1 and 2 wherein the I-FLICE-2 polypeptide inhibits apoptosis mediated by TNFR-1 and CD95 (Figure 6).

With the exception of the specific isolated I-FLICE-2 comprising SEQ ID NO: 6 or an Fc fusion protein comprising SEQ ID NO: 6, there is adequate written description about the structure associated with function of all polypeptide having an amino acid sequence at least 95% identical to amino acid sequence selected from the group consisting of: (a) amino acids from about 1 to about 75 in SEQ ID NO: 6; (b) amino acids from about 76 to about 252 in SEQ ID NO: 6; (c) amino acids from about 253 to about 348 in SEQ ID NO: 6; (d) amino acids from about 1 to about 348 in SEQ ID NO: 6; (e) amino acids from about 2 to about 348 in SEQ ID NO: 6 without the amino acid sequence. Further, the term "about" extends the upper and lower limits of the amino acids residues in SEQ ID NO: 6 as set forth in claim 9, 13-17, and 19-23. There is insufficient written description about the function of such polypeptide, much less about the structure of the epitope bearing portion of any polypeptide mentioned above.

With regard to claim 21, the term "having" or "comprises" is open-ended. It expands the polypeptide fragment such as the ones recited in claim 21 to include additional amino acids at either or both ends. There is adequate written description about the structure associated with function of the antigenic region having additional undisclosed amino acids to either or both ends to amino acids residues from about 62 to about 136 in SEQ ID NO: 6, or amino acid residues from about 184 to about 193 in SEQ ID NO: 6 or amino acid residues from about 205 to about 341 in SEQ ID NO: 6.

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Further, the specification discloses only fusion protein comprising the isolated I-FLICE polypeptide comprising SEQ ID NO: 6 fused to only Fc as the only heterologous polypeptide, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species of polypeptide, "heterologous polypeptide" and fusion protein to describe the genus for the claimed method. Thus, Applicant was not in possession of the claimed genus. See *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398; *University of Rochester v. G.D. Searle & Co.*, 69 USPQ2d 1886 (CA FC2004).

Applicant is directed to the Final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

12. Claims 9, 13-17, and 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "about" in claims 9, 13, 15, 17, 19, and 22 together with "95% sequence identity" is ambiguous and indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

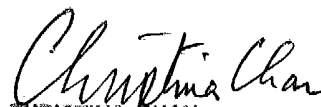
The term "about 1 to about 348 in SEQ ID NO: 6" in claims 14 is indefinite because the term "about" broadening the SEQ ID NO: 6 from about 1 to about 348. However, SEQ ID NO: 348 has only 348 amino acids and it is not clear which other amino acids to be included in "about 348 in SEQ ID NO: 6". It is suggested that the claim be amended to recite "The isolated I-FLICE-2 polypeptide claim 9, wherein the amino acid sequence comprises amino acids from 1 to 348 in SEQ ID NO: 6".

The term "about 2 to about 348 in SEQ ID NO: 6" in claims 16 is indefinite for the same reasons stated above. It is suggested that the claim be amended to recite "The isolated I-FLICE-2 polypeptide claim 9, wherein the amino acid sequence comprises amino acids from 2 to 348 in SEQ ID NO: 6".

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.
14. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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